REMARKS

Status of the Application

Claims 1-3 are pending. Claims 1-3 are rejected under 35 USC 112, first paragraph, for not providing enablement for treating AIDS. Claims 1-3 are also rejected under 35 USC 112, second paragraph. No art rejection is made to the claims.

Applicants provide herewith a Declaration and clinical trial results to show that the prescription according to the present invention can be used to treat AIDS, and various AIDS symptoms can be alleviated by the treatment. Applicants have amended claims 1-3 to address the 112, 2nd paragraph, rejection. No new matter adds through the amendments. For the reasons discussed below, withdrawal of the rejections is requested.

Claim Rejections- 35 U.S.C. 112, First Paragraph

Claims 1-3 are rejected under 35 USC 112, first paragraph, for not providing enablement for treating AIDS.

The Office Action cited Mirken (AIDS Treat News, 2000 Apr. 21; (341): 4-6) to disqualify CD4 cell count as having any meaningful correlation with treatment of AIDS. Mirken cites that "AIDS medicine has made a serious mistake by relying on laboratory markers such as CD4 cell counts, and viral load...There markers are criticized as unreliable at best and devious effort to hide the failure of HIV/AIDS science at worst...", and "all HIV and viral load tests as well as T-cell counts need to be banned immediately because they are useless indicators of a person's health".

Applicant respectfully disagrees.

At present, the basic mainstream theory of AIDS is that, AIDS has a close relationship with HIV and CD4 cells, and this is the basis for most experts to treat AIDS. Governments around the world formulate relevant administration measures and statistical references according to this theory. For more related information, please refer to USA CDC website (http://www.cdc.gov/hiv/topics/basic/index.htm and http://aids.gov/basic/faq/).

The above cited opinions believe that there is no correlation between HIV load, CD4 cell and AIDS. However, this is only a minority viewpoint. As indicated by Mirken in the same article (AIDS Treat News, 2000 Apr. 21; (341): 4), "The self-styled "AIDS dissidents," groups and individuals advocating the view that HIV does not cause AIDS, and often urging people with HIV

to reject medical care, have raised their profile in recent months, ratcheting up their advocacy in the U.S. and attempting to influence the health policies of foreign governments", "most [of the "AIDS dissidents"] reject the vast majority of conventional HIV/AIDS treatment, especially use of drugs to combat HIV". There are overwhelmingly more experts opposing this viewpoint. We believe that this viewpoint still needs further study, and this minority viewpoint cannot completely overthrow the current mainstream theory for treating AIDS. This viewpoint cannot overthrow the current medical accomplishments based on the correlation between HIV load, CD4 cells and AIDS. No definite proof shows that there is no correlation between HIV load, CD4 cell and AIDS.

The Office Action asserted that CD4 counts can be lower than average for reasons not related to AIDS. Even this is true, it cannot negate the relationship between CD4, HIV load and AIDS. The prescription of the present invention is used for treating AIDS patients or HIV carriers, not for just any patients. The prescription of the present invention is able to increase CD4 cells for AIDS/HIV patients.

The Office Action further indicated that "The invention only provides the description of a medicine preparation for increasing CD4 counts in AIDS patients up to 30 %, and no description regarding whether CD4 counts are normal at the end of the treatment or it will stay 30% increased after 6 month treatment duration". Therefore, it is not enabled for treating AIDS.

Clinical trial of the medicine prescription of the present invention has been conducted from October, 2002 to June, 2003. The clinical trial is conducted according to the specifications in GCP (Good Clinical Practice) in five clinical centers in China, and the trial results indicate that this prescription was effective for treating AIDS, and various AIDS symptoms were alleviated, such as alopecia, fatigue, emaciation and diarrhea, etc. In a treatment course of 6 months, CD4 count is increased by more than 30% in 50.57% patients. Because of the useful utility of the present invention, the prescription based on the present invention has been approved by China State Food & Drug Administration. The drug prepared based on this prescription has obtained new drug license issued by China State Food & Drug Administration. Case histories of some patients during the clinical trial are shown in the attached Appendix 1. A Declaration of the inventors is also enclosed herewith.

Furthermore, for AIDS patients, increase in CD4 count means enhancement of immunity and improvement of resistance against opportunistic infection, so the invention is effective for treating AIDS. Treatment is a process. Based on the current knowledge on AIDS and present

therapeutic procedures, currently there is no therapy that can cure AIDS completely. Applicants never claim that the present invention can cure AIDS, but it is useful for treating AIDS as shown in the provided evidence. As stated in MPEM 2111 VI, "The fact that there is no known cure for a disease, however, cannot serve as the basis for a conclusion that such an invention lacks utility. Rather, Office personnel must determine if the asserted utility for the invention is credible based on the information disclosed in the application."... "An assertion that the claimed invention is useful in treating a symptom of an incurable disease may be considered credible by a person of ordinary skill in the art on the basis of a fairly modest amount of evidence or support". Applicants believe that such required "fairly modest amount of evidence or support" has been provided in this case. It is not required that the invention must be able to cure AIDS patients for it to be useful and enabling.

The Office Action further indicated that "Considering this evidence, the skilled artisan would necessarily need to perform tedious trial and error protocols without expectation of success in order to treat AIDS".

As well established, the test of enablement is whether undue experimentation is needed to practice the invention. When determining whether the experimentation is undue, time and difficulty of experiments are not determinative if they are merely routine. See MPEP 2164.06. The present application gives the proportional boundary of various components in the medicine preparation, describes how to make tablets from the raw materials, how to treat the patients with the tablets, and how to evaluate the therapeutic effects. Therefore, the experiments are merely routine by following the instructions of the specification. In addition, the specification also describes a preferred embodiment of the present invention (Example 2, claim 2).

For reasons discussed above, the present invention is useful and enabling. Withdrawal of the rejection is requested.

Claim Rejections- 35 U.S.C. 112, Second Paragraph

Claims 1-3 were rejected under 35 USC 112, second paragraph. More specifically, the phrase "Chinese medicine preparation" is deemed indefinite, and the amount and unit of raw materials are not clear.

In response, Applicants have replaced the phrase "Chinese medicine preparation" with "medicine preparation" in the claims.

The amounts of raw materials recited in the claims are in weight proportion. Applicants have amended the claims to specify the amounts of raw materials are measured as weight unit. As the amounts are in weight proportion, the weight unit could be microgram, gram, kilogram, or other unit.

It is believed the amendments made to the claims overcome the rejections. Withdrawal of the rejection is requested.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the remaining claims are now in condition for allowance. Allowance of this application is earnestly solicited.

Respectively submitted
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